K131254

Kimberly-Clark Corporation

June 17, 2013

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant	Kimberly-Clark* 1400 Holcomb Bridge Road Roswell, GA 30076
Official Correspondent	Marcia Johnson, RAC, CBA Technical Leader, Regulatory Affairs Tel: 770.587.8566 Fax: 920.380.6351 email: marcia.johnson@kcc.com
Trade Name:	Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes
Classification Name:	Tracheal tube
Device Classification and Product Code	Class II per 21 CFR §868.5730 Product Code - BTR
Predicate Device	The Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes subject of this submission are substantially equivalent to the KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes cleared in 510(k) K120985.
Device Description:	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are available in adult sizes 7.0, 7.5, 8.0, 8.5 and 9.0mm with a Murphy

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Eye. They include a separate lumen with a dorsal opening above the cuff to provide access to the subglottic space. The subglottic space is reached via a normally open suction valve which includes a one-way port for rinsing the subglottic space with sterile saline (0.9% Sodium Chloride solution) or administering an air bolus to assist in maintaining a patent suction lumen patency. These devices are sold as disposable, sterile, single use, devices.

Intended Use:

KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are indicated for airway management by oral intubation of the trachea and for removal of secretions that accumulate in the subglottic space.

Technological Characteristics

Both the modified Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes and the predicate KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes have the same basic fundamental technological characteristics. Both are polyvinylchloride tubes with a barrel-shaped polyurethane inflatable cuff and a suction lumen. Both incorporate a suction valve with integrated rinse port to aid in removing secretions that accumulate in the subglottic space. The only difference in the endotracheal tube is the change in a raw material used to bond the cuff to the endotracheal tube. Below is a comparison table that summarizes the technological characteristics of the subject and predicate tubes.

	Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes (120985)	**Device subject of this submission**
Materials		
Endotracheal Tube	PVC tube w/Barium Sulphate Radiopaque line	Same
Pilot Balloon Assembly	PVC Pilot Balloon One-way valve (Bespak Check Valve) = PVC, Nitizile/Acetal/stainless steel Inflation Tube/tail = PVC	Same

Materials	Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes (120985)	Device subject of this submission
Inflatable Pressure Cuff	Polyurethane with a barrel-shape	Same
Suction System/Flush Port	PVC Tube with Acrylonitrile Butadiene Styrene (ABS) Valve	Same
Vent Connector	Polypropylene	Same
Ink	All inks were confirmed to be non-cytotoxic, non-irritating and non-sensitizing through appropriate ISO 10993 testing.	Same
Adhesives	UV-Cure Adhesives, Cyanoacrylate Adhesive	Same, except the adhesive used to bond the cuff to the tube has changed from an adhesive to a solvent based blend of materials.
Sizes	7.0, 7.5, 8.0, 8.5, 9.0 (mm)	Same
Shelf-life	2 years	Same

Summary of Testing:

Bench-top performance testing was conducted to confirm suctioning efficiency and additional bench-top testing was conducted to assure conformance to the following standards.

- ISO 5361:1999, Anesthetic and respiratory equipment - Tracheal tubes and connectors.

Biocompatibility testing was conducted to assure conformance to the following standards:

- ANSI/AAMI/ISO 10993-3: 2003 Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity,
- ANSI/AAMI/ISO 10993-5:2009, Biological evaluation of

medical devices - Part 5: Tests for In Vitro cytotoxicity
- ANSI/AAMI/ISO 10993-6, 2007 Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation
- ANSI/AAMI/ISO 10993-10: 2010: Biological evaluation of medical devices - Part 10:Tests for Irritation and Skin Sensitization

Clinical testing was not conducted.

All results of testing met acceptance criteria and demonstrate no concerns of safety or effectiveness for the modified device.

Conclusion: The modified Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are substantially equivalent to the predicate device, Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes (K120985), in intended use, design, performance, principles of operation, and both are intended for single use. Test results confirm that the device is as safe and effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

Kimberly-Clark Corporation
Ms. Marcia Johnson, RAC, CBA
Technical Leader, Regulatory
1400 Holcomb Bridge Road
ROSWELL GA 30076

Re: K131254
Trade/Device Name: KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: June 20, 2013
Received: June 21, 2013

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K131254

Device Name: Kimberly-Clark* KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes.

Indications For Use:

KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes are indicated for airway management by oral intubation of the trachea and for removal of secretions that accumulate in the subglottic space.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schulthels Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131254